



DEPARTMENT OF HEALTH & HUMAN SERVICES

Purged by *H. Dries* 9/25/97 1936
Public Health Service
HFI-35

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

458

September 24, 1997

WARNING LETTER
97-DT-18

Rick Ray, President
New Era Canning Co.
4856 First Street
New Era, Michigan 49446

Dear Mr. Ray:

An inspection of your canned vegetable processing operations was conducted by Investigator Kelley Clark on August 19 through 21, 1997. This inspection revealed significant deviations from the regulations set forth in Title 21, Code of Federal Regulations Part 110 (21 CFR 110), Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and Part 113 (21 CFR 113), which specifically covers the processing of Low Acid Canned Foods (LACF). The deviations observed during this inspection cause your products to be adulterated within the meaning of Section 402(a)(3) and/or (a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Specifically,

1) The failure to detect critical control factor deviations during production and/or record review and the failure to record the actions taken in response to deviations noted during processing and/or record review indicates the lack of an adequate quality control program, as required by 21 CFR 110.80, and a failure to comply with Current Good Manufacturing Practices, as specified in 21 CFR 113.5.

2) Low acid canned food processing deviations are not always detected and identified as such during processing or record review and are thus not being submitted for evaluation as required by 21 CFR 113.89. For example, your firm did not detect:

- a) The absence of a satisfactory initial temperature prior to the cook of asparagus in retort 6 on May 15, 1995. The deviation was apparently not noted by the operator at the time of processing. The deviation was not noted as detected during record review. The records do not indicated the reason for the lack of an adequate initial temperature for this lot. Maintaining a minimum initial temperature prior to cook is a critical control factor on your scheduled process for asparagus.

- b) Temperatures below your scheduled process temperature during the processing of green beans in the continuous cooker on August 11, 1997.
 - c) Temperatures below your scheduled process temperature during the processing of green beans in the continuous cooker on July 25, 1997.
- 3) Records do not reflect that deviations outside of operating parameters are being detected, or that corrective action is being taken, as a result of the supervisory or quality control review. For example, there is no record of any corrective action being taken to assure the adequacy of the cook and the accuracy of the processing records when the processing records contain recording charts reflecting higher processing temperatures than the mercury in glass thermometer readings.
- 4) Operators do not appear to understand the significance of temperature discrepancies between the mercury in glass thermometer and the recording thermometer. On August 21, 1997, Investigator Clark noted disagreement between the mercury in glass thermometer [REDACTED] F] for the cooker and the recording thermometer [REDACTED] F]. Although the operator accurately recorded these two temperatures, no corrective action was taken by the operator and the operator did not appear to understand the significance of the discrepancy. Despite recording thermometer charts for the [REDACTED] continuous cook retort recording higher temperatures than the recorded mercury in glass thermometers, no corrective action was taken on other dates. For example; July 25, 1997 from 2200 to 2300, August 7, 1997 from 0700 to 2300 and August 8, 1997 from 0700 to 1430.
- 5) Low acid canned food processing records are not reviewed for adequacy and completeness within one day of processing, as required by 21 CFR 113.100(b)(7). For example: Processing records for production on August 6, 1997 were not reviewed until August 11, 1997. Processing records for production on August 11, 1997 were not reviewed until August 14, 1997. Operator check records for August 7, 1997 were not reviewed until August 12, 1997.
- 6) The amount of product produced cannot always be reconciled with the amount of product placed on hold or destroyed. Specifically, records do not clearly show the disposition of the 5/15/95 asparagus cook from retort #6.

Some of these deviations were included in a list of Inspectional Observations (FDA-483) which was issued to you at the conclusion of the inspection. Neither the list of Inspectional Observations nor the above information is intended to be an all-inclusive list of deviations which may be present at your firm. It is your

Page 3

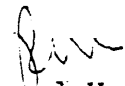
responsibility to assure that all of your firm's products comply with the requirements of the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to make prompt corrections may result in regulatory action, such as seizure or injunction, without further notice.

Please notify this office in writing, within 15 working days of your receipt of this letter, the current status of any products which had critical control factor deviations during production, of the specific steps you have taken or intend to take to correct the above-mentioned violations and any actions you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be implemented.

Your response should be directed to Sandra Williams, Compliance Officer, as the above address.

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District

cc:
EF
HFS-600
HFA-224
HFC-210 (1811662)
HFI-35 (purged)
GRRP
RF
legal jacket
warning letter book
FOI team
Mich. Dept. Ag.
RVM
SW
Food Team
RVM/SW/chs

